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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOX:KET NO.	CONFIRMATION NO.
10/023,839	12/21/2001	Richard Derose	022650-685	4793
7590 04/20/2005			EXAMINER	
Norman H. Stepno			HELMER, GEORGIA L	
BURNS, DOANE, SWECKER & MATHIS, L.L.P. P.O. Box 1404 Alexandria, VA 22313-1404			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

U.S. Patent and Trademark Office PTOL-326 (Rev. 1-04)

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date \_\_\_

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)

4) Interview Summary (PTO-413)

Paper No(s)/Mail Date. \_\_\_

5) Notice of Informal Patent Application (PTO-152)

#### **Office Action**

### Status of the Claims

- 1. The Office acknowledges receipt of Applicants Response; dated 2 November 2004, and of Applicant's terminal disclaimer over US 6,388, 961.
- 2. Applicant has amended claim 1. Claim 1 is pending, and is examined in the instant action.
- 3. This action is made FINAL necessitated by Applicant's amendment.
- 4. All rejections not addressed below have been withdrawn.
- 5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

## Claim Rejections - 35 USC § 112-written description

6. Claim 1 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant traverses that the invention of claim 1 as amended, is described in the specification by reference to representative species described there and taken together with the information in the specification and the examples of how to make and use the claimed invention (Response, p. 6), citing Example 2, parts 2 and 3, wherein two different representative histone H3.3 genes from Arabidopsis thaliana are exemplified. Applicant states that all introns have consensus sequences in the 5' and 3' splice sites

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and these are known to the skilled person as evidenced by Sinibaldi, 1992 (Response, p. 7). Applicant's traversal is unpersuasive. Applicant has not provided any structure associated with the claimed invention. Applicant has described the 5' intron from two Arabidopsis thaliana H3.3 genes isolated by them. Applicant has not defined a size or size range of the 5' region in which the expected 5' intron would occur; thousands of kb of DNA are 5' to the claimed sequence. Nor has Applicant defined a size range of an expected intron.

### Claim Rejections - 35 USC § 112-enablement

- 7. The following is a quotation of the first paragraph of 35 U.S.C. 112:
  - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 8. Claim 1 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant traverses that the experimentation would not be undue because the H3.3 histone genes are a very highly conserved family of amino acid sequences and can be thereby identified (Response, p. 9). Given that the claimed intron is known to be in the 5' region of the gene, the existence of intron consensus sequences, together

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with the H3.3 conservation would allow the identification of other such sequences.

Applicant provides (Exhibit A) a BLAST search which "show that the histone H3.3 from

rice and vine share 100% identity with the one of Arabidopsis thaliana from which the

intron disclosed in the Examples. Applicant's traversal is unpersuasive. Applicant has

provided information on the 5' regions of two H3.3 histone genes of Arabidopsis

thaliana, a dicot angiosperm. Applicant's information (Exhibits) provided on the DNA

sequence similarity of the H3.3 gene themselves does not enable all plant 5' H3.3

introns. It is further noted that the sequence from rice is of a "putative" H3.3.

invention is not enabled throughout the broad scope of the claims.

Therefore, given the breadth of the claims; the lack of guidance; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the

### Remarks

- 9. No claim is allowed.
- 10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0976. The examiner can normally be reached on 8:30 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia L. Helmer Patent Examiner

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23 June 2004

AMY J. NELSON, PH.D SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600